

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

John W. Lynn

ATTENTION:

Director of Technology Center 3640

Serial No. 10/603,134

(MPEP § 1002.02(c), par. (3))

Filed: June 24, 2003

For: "Enhancing Maturation of Oocytes in Bivalves" (Attorney File No. 0119.1)

PETITION TO THE DIRECTOR OF TECHNOLOGY CENTER 3640

UNDER 37 C.F.R. §§ 1.104 and 1.181 TO REVIEW PROPRIETY OF OFFICE ACTION

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

This Petition is filed to request that the Director of Technology Center 3640 review the propriety of the October 5, 2004 office action, a copy of which is attached for convenience of reference.

CERTIFICATE

I hereby certify that this Petition and the accompanying check for \$130 are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on October 21, 2004.

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John H. Runnels

Registration No. 33,451

October 21, 2004

The October 5, 2004 office action rejected all Claims, on both indefiniteness grounds and prior art grounds. This Petition seeks review of the propriety of the prior art rejections. This Petition does not seek review of the merits of the prior art rejections, which would, of course, ultimately be reviewable by appeal. Rather, this Petition seeks review of whether the Examiner has even written proper prior art rejections in the first instance, whether it is even possible for the Applicant to provide a meaningful response on the merits to the prior art rejections as currently written.¹

The Examiner has taken the entire background section of the present specification, including both its general discussion and its citations of specific references, and lumped it into a single, artificial entity that the Examiner has designated as "Applicant's Admitted Prior Art." Without any evident analysis, the Examiner then simply concluded that the claims were either anticipated or obvious over the undifferentiated "Admitted Prior Art."

Applicant respectfully requests that the October 5, 2004 office action be withdrawn, and that a new office action be prepared and mailed, a new action that complies with 37 C.F.R. § 1.104 and M.P.E.P. § 707.07(g).

The prior art rejections are so vague that it is hardly possible to prepare a meaningful reply. The Director is respectfully requested to direct the Examiner to prepare and mail a more definite office action, and to start a new period for response. If any prior art ground of rejection should be entered in the new action, then the Examiner should be required to specify with particularity what portions of any prior art references are being relied upon, and why the cited portions are said either to anticipate the claimed inventions, or why it would have been obvious to modify the cited portions to make the claimed inventions.

It is respectfully submitted that the October 5, 2004 office action does not comply with 37 C.F.R. §1.104. Below are excerpts from 37 C.F.R. §1.104(a)(1), (a)(2), (b), and (c)(2):

¹Review of the indefiniteness rejection is not requested at this time. While Applicant respectfully disagrees with the indefiniteness rejection, it is nevertheless reasonably clear what was intended by the indefiniteness rejection, and how an ordinary response to that rejection might be prepared in due course. By contrast, it is hardly possible to prepare a meaningful response to the October 5, 2004 prior art rejections.

The examination shall be complete with respect . . . to the patentability of the invention as claimed

The reasons for any adverse action or any objection or requirement will be stated in an Office action and such information or references will be given as may be useful in aiding the applicant . . . to judge the propriety of continuing the prosecution.

The examiner's action will be complete as to all matters

In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practical. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.

See also M.P.E.P. § 707.07(g):

Piecemeal examination should ordinarily be avoided as much as possible. The examiner ordinarily should reject each claim on all valid grounds available, avoiding, however, undue multiplication of references.

Disregarding these principles, the Examiner instead said that the entire background section of the present specification, including both its general discussion and its citations of specific references, would be lumped into a single, artificial entity that the Examiner has designated as "Applicant's Admitted Prior Art." Without any evident analysis, the Examiner then simply concluded that the claims were either anticipated or obvious over the undifferentiated "Admitted Prior Art." The Examiner offered no supporting details or rationale.

² For the record, Applicant does not acknowledge that everything in the general discussion appearing at paragraphs [0003] to [0026] of the specification in fact constitutes prior art under the patent statute. Certainly, the discussion touches upon much that is part of the prior art. But the Applicant has nowhere admitted, as the Examiner has suggested, that everything in that section is necessarily part of the prior art. A different situation would be presented if the Examiner had focused on an individual statement, and if the Examiner had addressed whether the Applicant had acknowledged that the particular statement reflected what was in the prior art. But the Examiner has not done so. Applicant has said nothing that could be fairly construed as an acknowledgment that everything appearing in paragraphs [0003] to [0026] of the specification necessarily constitutes prior art.

For example, the last paragraph on page 2 of the office action stated:

Claims 1, 2, 6-11, 13, 14, 16-18, and 21-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Applicant's Admitted Prior Art (as set forth in [0003] to [0026]] of the specification; hereinafter is referred to as AAPA).

The Examiner's entire analysis of independent Claim 1 appears in the first full paragraph on page 3 of the office action (which is quoted in full below). In that paragraph the Examiner summarily concluded, with no evident analysis, that the invention of independent Claim 1 was disclosed in the "Admitted Prior Art." The language of this paragraph is almost entirely a verbatim repetition of the language of Claim 1. There was no indication as to where in the prior art any of the limitations of Claim 1 might be found. Nor was there any recognition that, for a proper rejection under § 102, all the limitations of a claimed invention must appear in a single prior reference. Even if, for the sake of argument, one agreed with the Examiner that each of the limitations appeared somewhere in the prior art (which Applicant does not acknowledge, but posits merely for the sake of argument), it still would not follow that the claimed invention was anticipated. Anticipation under § 102 requires that all limitations must appear in a single reference. Please note that in the following paragraph, which reproduces in full the Examiner's entire analysis of Claim 1, the added *italics* denote language that is verbatim identical to the language of Claim 1, aside from changes in indentation. Only the non-italicized portion of the following paragraph represents the Examiner's own words:

AAPA discloses a method for maturing and releasing oocytes in a bivalve, said method comprising the sequential steps of: (a) administering to a living, intact bivalve an effective amount of a maturation stimulus comprising exogenous estrogen or an exogenous estrogen agonist; (b) allowing oocytes in the bivalve to mature in response to the maturation stimulus; wherein substantially more oocytes mature than would mature on average in the same time in an

otherwise identically-situated bivalve that had not been administered the maturation stimulus; and (c) administering to the bivalve an effective amount of a spawning stimulus; whereby the bivalve releases mature oocytes; wherein substantially more mature oocytes are released than would be released on average by an otherwise identically-situated bivalve that had not been administered the spawning stimulus; wherein the spawning stimulus is selected from the group consisting of exogenous serotonin, an exogenous serotonin agonist, an exogenous serotonin uptake inhibitor, heat shock, sperm extract, or other spawning stimulus. Further note that the sequential order of the steps is an inherent feature within AAPA's method since these steps must be carry out in that order to ensure a proper maturing and releasing of oocytes in bivalves.

The Examiner's treatment of the various dependent Claims under §§ 102 and 103 was similarly superficial. This Petition will not be lengthened by a discussion of the rejections of the dependent Claims. In general, the office action stated only a conclusion that the "AAPA" further disclosed the limitations of the dependent claims, or that those limitations were obvious over the "AAPA" as a "matter of design choice," or the like.

In only a single case, found in paragraph 7 bridging pages 6 and 7, did the Examiner even purport to refer to any specific, individual reference. Namely, WO 96/15662 was cited as part of a rejection of Claim 12. But even there, the Examiner did not specify what portion of the '662 publication was being cited, nor what portion of the "AAPA" was being combined with the '662 publication.

Applicant recognizes that an admission by an applicant can, in an appropriate case, be treated as if it were prior art. However, even in such a case the Examiner must specify with particularity just what the alleged admission is, and how the Examiner is relying upon that admission. Furthermore, a statement must appear somewhere in the specification or in the prosecution history that may fairly be construed as an admission that the statement is part of the "prior art." See M.P.E.P. § 2129. The Examiner has identified no such admissions. The Examiner should be cautioned not to treat some statement as "admitted prior art" merely because it appears as part of the application's general background discussion. The Examiner should also be cautioned that an invention is not anticipated merely because all the sub-components of the claimed invention might appear somewhere

in the prior art. Anticipation requires instead that all limitations be satisfied by a single reference.

It is respectfully submitted that it is hardly possible for the Applicant to prepare a meaningful reply to the prior art rejections in the October 5, 2004 office action. It is respectfully submitted that the office action fails to comply with 37 C.F.R. § 1.104 and M.P.E.P. § 707.07(q).

Miscellaneous

This paper is being filed timely under 37 C.F.R. § 1.181(f). From an abundance of caution, if any extension of time is required, please consider this paper a petition for the total extension of time required.

A check for the \$130 petition fee is enclosed. If this amount is incorrect, please charge any deficiency, or credit any excess to Deposit Account 20-0096.

Conclusion

The October 5, 2004 Office Action should be withdrawn. A new, non-final Office Action should be prepared and mailed, an Action that addresses the merits of each of pending Claims 1-23. The new action should comply with 37 C.F.R. § 1.104 and M.P.E.P. § 707.07(g), and should set forth with particularity the basis for any rejections, where applicable citing specific portions of specific references. The new action should restart the period for response.

Respectfully submitted,

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October 21, 2004



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,134	06/24/2003	John W. Lynn	0119.1 Lynn	9894
25547	7590 10/05/2004		EXAMINER	
PATENT DEPARTMENT TAYLOR, PORTER, BROOKS & PHILLIPS, L.L.P P.O. BOX 2471			NGUYEN, TRINH T	
			ART UNIT	PAPER NUMBER
BATON ROU	JGE, LA 70821-2471		3644	
			DATE MAILED: 10/05/2004	4

Please find below and/or attached an Office communication concerning this application or proceeding.



OF		0.5		
0	Application No.	Applicant(s)		
OCT 25 2004 E	10/603,134	LYNN, JOHN W.		
Some Action Summary	Examiner	Art Unit		
The MAILING DATE of this communic	Trinh T Nguyen	3644		
The MAILING DATE of this communic	ation appears on the cover sheet wi	th the correspondence address		
A SHORTENED STATUTORY PERIOD FOR THE MAILING DATE OF THIS COMMUNIC - Extensions of time may be available under the provisions of after SIX (6) MONTHS from the mailing date of this commun - If the period for reply specified above is less than thirty (30) - If NO period for reply is specified above, the maximum statu - Failure to reply within the set or extended period for reply will Any reply received by the Office later than three months afte earned patent term adjustment. See 37 CFR 1.704(b).	ATION. 37 CFR 1.136(a). In no event, however, may a relication. days, a reply within the statutory minimum of thirt tory period will apply and will expire SIX (6) MON II, by statute, cause the application to become AB	eply be timely filed y (30) days will be considered timely. THS from the mailing date of this communication. ANDONED (35 U.S.C. § 133).		
Status				
1) Responsive to communication(s) filed	on <u>24 <i>Jun</i>e 2003</u> .			
2a) ☐ This action is FINAL . 2b) ☐ This action is non-final.				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is				
closed in accordance with the practice	under <i>Ex parte Quayl</i> e, 1935 C.D	. 11, 453 O.G. 213.		
Disposition of Claims				
4) Claim(s) 1-23 is/are pending in the appear 4a) Of the above claim(s) is/are 5) Claim(s) is/are allowed. 6) Claim(s) 1-23 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction	withdrawn from consideration.			
Application Papers				
9) The specification is objected to by the B 10) The drawing(s) filed on is/are: a Applicant may not request that any objection Replacement drawing sheet(s) including the short of t	a) accepted or b) objected to long on to the drawing(s) be held in abeyangle correction is required if the drawing(ce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for a) All b) Some * c) None of: 1. Certified copies of the priority do 2. Certified copies of the priority do 3. Copies of the certified copies of application from the Internationa * See the attached detailed Office action for	ocuments have been received. Incuments have been received in A the priority documents have been all Bureau (PCT Rule 17.2(a)).	pplication No received in this National Stage		
Attachment(s)				
1) Notice of References Cited (PTO-892)		ummary (PTO-413)		
 Notice of Draftsperson's Patent Drawing Review (PTO 3) Information Disclosure Statement(s) (PTO-1449 or PT Paper No(s)/Mail Date 6/24/03.)/Mail Date formal Patent Application (PTO-152)		

Art Unit: 3644

DETAILED ACTION

Claim Rejections - 35 USC § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 - The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 2. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrases "the same time in an otherwise identically-situated bivalve" and "an otherwise identically-situated bivalve" are confusing because it is unclear as to what are being claimed.

In claim 4, the phrase "an otherwise identically-situated bivalve that is not treated in accordance with the recited method" is confusing because it is unclear as to what is being claimed.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- 4. Claims 1, 2, 6-11, 13, 14, 16-18, and 21-23 are rejected under 35 U.S.C. 102(a) as being anticipated by Applicant's Admitted Prior Art (as set forth in [0003] to [0026] of the specification; hereinafter is referred to as AAPA).

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AAPA discloses a method for maturing and releasing oocytes in a bivalve, said method comprising the sequential steps of: (a) administering to a living, intact bivalve an effective amount of a maturation stimulus comprising exogenous estrogen or an exogenous estrogen agonist; (b) allowing oocytes in the bivalve to mature in response to the maturation stimulus; wherein substantially more oocytes mature than would mature on average in the same time in an otherwise identically-situated bivalve that had not been administered the maturation stimulus; and (c) administering to the bivalve an effective amount of a spawning stimulus; whereby the bivalve releases mature oocytes; wherein substantially more mature oocytes are released than would be released on average by an otherwise identically-situated bivalve that had not been administered the spawning stimulus; wherein the spawning stimulus is selected from the group consisting of exogenous serotonin, an exogenous serotonin agonist, an exogenous serotonin uptake inhibitor, heat shock, sperm extract, or other spawning stimulus. Further note that the sequential order of the steps is an inherent feature within AAPA's method since these steps must be carry out in that order to ensure a proper maturing and releasing of oocytes in bivalves.

For claim 2, AAPA further discloses the bivalve is not killed before the release of oocytes.

For claim 6, AAPA further discloses the matured oocytes are released substantially in synchrony.

For claim 7, AAPA further discloses the bivalve is a triploid.

For claim 8, AAPA further discloses the bivalve is a tetraploid.

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For claim 9, AAPA further discloses the bivalve is a female.

For claim 10, AAPA further discloses the bivalve has an indifferent gonad, wherein said method additionally induces the bivalve to develop as a female.

For claim 11, AAPA further discloses the bivalve is a hermaphrodite.

For claim 13, AAPA further discloses the bivalve is Crassostrea gigas.

For claim 14, AAPA further discloses the bivalve is Patinopecten yessoensis.

For claim 16, AAPA further discloses the maturation stimulus comprises estradiol-I7B, and wherein the spawning stimulus comprises serotonin.

For claim 17, AAPA further discloses the spawning stimulus comprises fluvoxamine.

For claim 18, AAPA further discloses the spawning stimulus comprises treatment with heat shock or sperm extract.

For claim 21, AAPA further discloses the spawning stimulus comprises a serotonin agonist.

For claim 22, AAPA further discloses the spawning stimulus comprises a serotonin uptake inhibitor.

For claim 23, AAPA further discloses the maturation stimulus comprises an estradiol-I7B agonist.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

>,

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 3-5, 15, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (as set forth in [0003] to [0026] of the specification; hereinafter is referred to as AAPA).

For claims 3 and 5, it would have been obvious to one having ordinary skill in the art at the time the invention was made to allow the bivalve to rest for a time after the release of oocytes and wherein the same method is subsequently applied again to the same bivalve so as to cause a subsequent release of oocytes from the same bivalve during the same breeding season, since it has been held that mere duplication of the essential steps for maturing and releasing oocytes involves only routine skill in the art.

For claim 4, AAPA discloses the claimed invention except for indicating that the subsequent release of oocytes occurs significantly earlier than a subsequent release of oocytes would occur on average in an otherwise identically situated bivalve that is not treated in accordance with the recited method. However, It would have been obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to have modified the method of AAPA so that the subsequent release of oocytes occurs significantly earlier than a subsequent release of oocytes, since it is believe that through trial and error during the experimental process that one comes up with the best result/solution to produce the most oocytes.

For claim 15, AAPA discloses the claimed invention except for indicating that the bivalve to release oocytes outside of the normal breeding season. However, It would have been obvious matter of design choice to one having ordinary skill in the art at the

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time the invention was made to have modified the method of AAPA so that the bivalve to release oocytes outside of the normal breeding season, since applicant did not provide a reason and/or showing any criticality as to why the bivalve have to release oocytes outside of the normal breeding season, and it is believe that through trial and error during the experimental process that one comes up with the best result/solution to produce the most oocytes.

For claim 19, AAPA discloses the claimed invention except for indicating the maturation stimulus is administered to the bivalve in a single dose. However, It would have been obvious matter of design choice to one having ordinary skill in the art at the time the invention was made to have modified the method of AAPA so that the maturation stimulus is administered to the bivalve in a single dose, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art, and it is believe that through trial and error during the experimental process that one comes up with the best dose to produce the most oocytes.

For claim 20, it would have been obvious to one having ordinary skill in the art at the time the invention was made to administrate the maturation stimulus to the bivalve in sequential doses over a period of time wherein the sequential doses may be constant or may increase over time, since it has been held that mere duplication of the essential steps for maturing and releasing oocytes involves only routine skill in the art.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (as set forth in [0003] to [0026] of the specification;

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hereinafter is referred to as AAPA) in view of WO 96/15662 (hereinafter is referred to as

WO'662).

AAPA discloses the claimed invention except for indicating that the bivalve is

Crassostrea virginica.

WO'662 teaches a similar method as that of AAPA in which WO'662's method

uses Crassostrea virginica. It would have been obvious to one having ordinary skill in

the art at the time the invention was made to have modified the method of AAPA so as

to include the use of Crassostrea virginica, in a similar manner as taught in WO'662,

since to do so would merely replace one old and well known bivalve with another old

and well known bivalve in order to realize the benefits thereof.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Trinh T Nguyen whose telephone number is (703) 306-

9082. The examiner can normally be reached on M-F (9:30 A.M to 6:00 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Teri Luu can be reached on (703) 305-7421. The fax phone number for the

organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Trinh T Nguyen Patent Ex. Art Unit 3644